tion. All this is still in the future but if current work is successful it could become practice within five or ten years. Presymptomatic detection of breast cancer could take its place with the cervical smear and mass radiography to provide a real advance in the management of the disease.

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The Presymptomatic Diagnosis of Lung Cancer

by G Z Brett MD
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One of the results of using mass radiography for large-scale screening of apparently healthy persons has been the discovery of unsuspected lung cancer in examinees without chest symptoms or none compelling medical consultation. It is in this wider sense that routine mass radiography has made it possible to arrive at a presymptomatic diagnosis of the disease.

In an earlier investigation carried out by the North West Metropolitan Mass Radiography Service it was found that the percentage of both resection and five-year survival after resection was, by chance, the same, 55% in lung cancer detected by routine mass radiography and 32% in patients referred for chest radiography by general practitioners (Brett 1959). The value of these results was, however, reduced by the fact that the rate of detection of the 'presymptomatic' cases was only 0·27 per thousand men of all ages, compared with a high yield of 26·7 per thousand in doctors' patients.

It seemed reasonable to assume that the low rate of detection of lung cancer by routine mass radiography was related to the conventional three-yearly or longer intervals between repetitive surveys of the population at risk and that to increase this rate routine surveys would have to be carried out at more frequent intervals and be directed towards men in the cancer age. In order to assess the feasibility and value of such surveys a study was needed which would be so designed as to give a valid answer to the following questions: (1) Were frequent (e.g. six-monthly) routine surveys practicable? (2) Would the detection of presymptomatic lung cancer be increased by such surveys? (3) Would six-monthly surveys affect the rate of resection? (4) Would lung cancer mortality be reduced in a population sample which was offered six-monthly examinations compared with one that was not?

The answer to most of these questions could have been obtained by investigating the lung cancer experience of one group of men subjected to frequent X-ray examinations. Since, however, it was also intended to assess the effect of this method on lung cancer mortality it was necessary to introduce into the study two population samples of which one, a test group, would be offered six-monthly X-ray examinations over a period of three years, while the other, a control group, would be X-rayed only at the beginning and the end of that period. The mortality from lung cancer in the two groups could then be compared. Both groups would be confined to men aged 40 and over. As an investigation on these somewhat complicated lines had not been attempted before, the planning and method of the scheme were empirical.

Method of Investigation

The basic requirement was to secure a sufficient number of male volunteers for the two groups in the scheme. Experience indicated that an approach to industry would provide from many aspects a more manageable scheme than dealing with individuals. During the two years preceding the actual X-raying of volunteers the number of men over 40 employed in industrial establishments of a suitable size was ascertained. The support of management and unions of the eligible firms for the aims of the research project was secured and their co-operation was of a high order. The firms, mainly factories, comprising about 75,000 potential volunteers, were sorted into two groups by a statistician. They were broadly cross-matched into type of work and area and the groups were finally divided into test and control by random sampling numbers. The test group consisted of 75 factories and the

control group of 44, which supplied a total of 55,034 volunteers for the two groups.[1] Each examinee completed a record card with details of age, occupation, address and health as well as smoking habits. The information was subsequently transferred to punch cards from which the final breakdown was carried out using the Hollerith system.

Material and Method of Follow Up

At the first survey 29,723 men were X-rayed in the test group and 25,311 in the control. In all, 162,231 X-ray examinations were carried out in the test group and 41,169 in the control group during the three years of the scheme. For the purpose of assessing lung cancer mortality in the two groups it was necessary to find out which persons of those who volunteered for the initial surveys were alive at the end of the three years and which were dead. All examinees in the test group, irrespective of whether they had attended the intermediate surveys, and all examinees in the control group were therefore followed up after the completion of the scheme. The method of following up was identical for the two groups (Table 1). Nearly two-thirds were traced by the ideal method of chest radiography at the final survey and a further 25% by letter to themselves or their employers, leaving about 10% untraced. In all those who were known to have died it was possible to establish the cause of death from hospital records and the General Register Office at Somerset House.

Table 1
Method of follow up

Method	*Test group* No.	%	*Control group* No.	%
Final X-ray examinations	18,789	63·2	15,858	62·6
Information from employer	4,022	13·5	3,076	12·1
By letter	3,988	13·4	3,470	13·7
Untraced	2,924	9·9	2,907	11·6
Originally in scheme	29,723	100·0	25,311	100·0

Results

Age and smoking habits: The age grouping and smoking habits of those in the test and control groups were almost identical (Tables 2 and 3). The figures may well be representative for industry as a whole.

[1]The large difference in the number of firms in the two groups arose because the firms were first aggregated in area groups and the groups then allocated at random to one or other series until one series contained approximately half the total number of employees available

Table 2
Populations at risk by age

Age	*Test group* No.	%	*Control group* No.	%
40–44	7,190	24·2	6,217	24·6
45–49	7,922	26·6	6,692	26·4
50–54	6,421	21·6	5,622	22·2
55–59	4,828	16·2	4,083	16·1
60–64	2,617	8·8	2,081	8·2
65–69	610	2·1	555	2·2
70+	135	0·5	61	0·3
Total	29,723	100·0	25,311	100·0

Table 3
Smoking habits of population at risk

	Test group No.	%	*Control group* No.	%
Non-smokers (includes pipe smokers)	3,584	12·0	2,998	11·8
Ex-smokers	5,601	18·8	4,962	19·6
Cigarette smokers	20,538	69·2	17,351	68·6
Total	29,723	100·0	25,311	100·0

Lung cancer: Table 4 shows the distribution of all cases of lung cancer as they are known to have occurred in both the test and control groups at the different periods of the investigation. Of the 126 cases in the test group 96 (76·2%) were detected by mass radiography and 37 (44·6%) of the 83 cases in the control group.

Table 4
Lung cancer detected during three years by source

	Initial survey	*Final survey*	*Unknown source*	*Six-monthly surveys*
Test group	31	6	30	59
Control group	20	17	46	–

From the analysis shown in Table 5 lung cancer discovered at the final surveys is excluded as no case was followed up beyond the three-year period. Of the 59 cases detected in the test group by six-monthly surveys 31 were alive and 28 were dead at the completion of the study. It was also found that 30 patients with lung cancer in the test group and 46 in the control, discovered elsewhere, had died in the intervening period between the first and last examinations. Of the 30 patients in the test group 7 had died within six months of

Table 5
Lung cancer in test and control groups by source and results of a three year follow up

	Test group			*Control group*	
	Initial survey	*Six-monthly surveys*	*Unknown source*	*Initial survey*	*Unknown source*
Alive	11	31	–	10	–
Dead	20	28	30	10	46
Total	31	59	30	20	46

Table 6
Lung cancer detection and resectability in test and control groups

	Test group		*Control group*	
	Initial survey	*Final survey after three years*	*Initial survey*	*Final survey after three years*
Number X-rayed	29,723	19,695	25,311	15,858
Number of cases	31	6	20	17
Detection rate per 1,000 examinations	1·0	0·3	0·8	1·0
Percentage of detected growths resected	51	50	71	65

their initial X-ray; the remainder had missed one or more of the six-monthly surveys. Of the 46 deaths in the control group, 3 had occurred within six months of the initial examination.

Detection and resectability: To estimate the rate of detection and the percentage of resected cases of lung cancer in this series, all cases detected during the three years of the scheme were taken into account. Table 6 shows that there was no significant difference in the rates of detection between the initial and final surveys of the control and the initial survey of the test group. These findings are not unexpected if it is borne in mind that the examinations were all carried out at approximately three-yearly intervals and that the age distribution of the subjects was similar. On the other hand, it can be seen that the detection rate in the final survey of the test group was substantially lower. This can be attributed to the fact that many cases of lung cancer had already been discovered at the intermediate examinations of this group.

In Table 7 the detection rates for the intermediate six-monthly surveys in the test group are shown to be remarkably constant. This made it possible to estimate the mean annual incidence of the disease as 0·9 per thousand examined. This figure may be too low since an appreciable proportion of examinees failed to attend at each subsequent survey.

The discovery of 65 cases of lung cancer by the six six-monthly surveys and the annual rate of detection resulting from it indicates the yield that could be expected each year and which would have been lost to this population sample had it not been subject to further frequent examinations after the initial survey. Of these 65 cases 42 (65%) were resected compared with 16 (51%) in the initial survey. It appears, therefore, that while more frequent X-ray examinations do not increase substantially the percentage of resection, they make it possible for more patients to have the growth removed.

Mortality: It has been shown in Table 1 that 9·9% of persons in the test group and 11·6% in the control have so far not been traced. For this reason the figures in Table 8 are incomplete. They are presented, however, for the purpose of indicating the direction in which lung cancer mortality in the two groups is moving.

For the purpose of calculation of the mortality rates from lung cancer in the two groups only the deaths that occurred during the three-year period between the initial and final surveys were taken into account. It was thought that, since it was the possible effect of six-monthly surveys on lung cancer mortality in the test group that was to be measured and compared with the control group, the inclusion of deaths that resulted from the initial surveys, conducted on different lines, might conceivably obscure this issue.

The mortality rate for the two population samples was therefore calculated on the basis of 58 deaths from lung cancer in the test group and

Table 7
Test group: lung cancer detection and resectability at six-monthly intervals

		Six-monthly surveys					
	Initial survey	*2nd*	*3rd*	*4th*	*5th*	*6th*	*7th*
Number X-rayed	29,723	24,623	23,082	22,638	21,778	20,592	19,695
Number of cases found	31	11	10	13	14	11	6
Detection rate per 1,000 examinations	1·0	0·4	0·4	0·6	0·6	0·5	0·3
Number resected	16	8	9	8	8	6	3
Percentage of detected growths resected	51	73	90	61	57	55	50

Table 8
Incomplete figures of annual lung cancer mortality in test and control groups (excluding cases detected at initial and final surveys)

	Test group			*Control group*		
Age	*No. observed*	*No. of deaths*	*Rate per 1,000*	*No. observed*	*No. of deaths*	*Rate per 1,000*
40–44	7,190	3	0·14	6,217	1	0·1
45–49	7,922	5	0·2	6,692	6	0·3
50–54	6,421	13	0·7	5,622	12	0·7
55–59	4,828	20	1·4	4,083	13	1·0
60–64	2,617	15	1·9	2,081	7	1·0
65–69	610	1	0·5	555	6	3·3
70+	135	1	2·5	61	1	5·7
Total	29,723	58	0·65	25,311	46	0·6

46 in the control. As has been shown in Table 5 the 58 deaths in the test group were made up of the 28 that had occurred among the cases of lung cancer discovered by six-monthly examinations and 30 deaths in persons in whom the diagnosis was made elsewhere. The annual mortality rate from lung cancer was in this analysis 0·65 per thousand in the test group and 0·6 per thousand in the control (Table 8).

Discussion and Conclusions

The aims of this study were first to assess the practical possibilities of shortening the interval between mass radiography surveys of men in the cancer age from three years to six months; and secondly to evaluate the effect that frequent X-ray examinations had on some aspects of lung cancer.

The results suggest that, given adequate preparation, six-monthly mass radiography surveys of men aged 40 and over are feasible. It has also shown that due to more frequent examination of the same population sample, 65 cases of lung cancer were discovered which would not have been found at that particular time had only three-yearly surveys been employed. On the other hand the percentage of resection in these 65 cases was not appreciably greater than that in lung cancer detected by conventional routine surveys. This finding can perhaps be explained by the following consideration:

During three-year or longer intervals between the usual routine mass radiography surveys, many patients with lung cancer will have developed symptoms and been diagnosed. It is reasonable therefore to assume that the lung cancer that remained to be diagnosed by the actual surveys would have a relatively short period of radiological detectability. This gap between the possible and the actual detection may not have been substantially greater in the cancer found in this group than in the cancer found at six-monthly surveys and could account for the similarity of the resection figures.

The annual mortality rate from lung cancer estimated on the basis of incomplete results was similar for the test and control groups. This may prove to be correct. It is, however, possible that in the 11·6% that remain to be traced in the control group more deaths are hidden than in the 9·9% in the test group, and also that three years is perhaps too short a period of observation to bring out differences in mortality which might become apparent later.

It seems therefore that if a reduction of mortality from lung cancer in a population at risk is considered to be the main criterion of the value of six-monthly mass radiography surveys, then this study has failed to produce such evidence. If, however, the merit of this method is measured by the discovery of a greater number of cases earlier than they would otherwise have been, so that more patients are given the chance of resection, then six-monthly examinations of men over the age of 40 are worth while.

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DISCUSSION

Dr Richard Doll
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When I was a student, it used to be said that some senior members of the staff spent their time disproving the value of treatments that other people had given up long before on inadequate evidence. That was intellectually a satisfying exercise, but not perhaps very rewarding; and I think there may be people who will say that the large-scale studies that have been discussed here fall into the same category. 'Surely,' they will say, 'it is quite obvious that if you can diagnose cancer at an earlier stage, you will do good.'

This might have been a reasonable attitude at the time when trying to get cancer diagnosed at an earlier stage consisted of educating doctors in how to recognize cancer more easily and educating patients to report to the doctor. Now, however, the techniques of early diagnosis are much more complicated, they are expensive in money and in manpower, and they cause some inconvenience to a very large number of people.

The sort of study that has been reported – trying to find out whether these campaigns to get earlier diagnosis have any beneficial result – is extremely worth while, for three reasons. If these studies get a positive result, this will justify the demand for considerably more money to make prophylactic services available to everyone. If, however, they provide negative results and show that we do not really gain anything worth while from them, this is just as important because it will release energy and money for other more fruitful purposes. Thirdly, whether the results are positive or negative, they cannot help but throw light on the mechanism by which cancer is produced – a subject of which we are still almost totally ignorant.

We are beginning to get indications of some of the factors that play a part in the production of cancer, and we are fairly confident that the disease is not the result of an all-or-none reaction but of a process. It is, moreover, a process that takes place over a long period and is affected by external agents, by hormonal influences and, in all probability, by immunological reactions; and it may be capable of being influenced to develop in one or other direction over a long period. If, as a result of these studies, we can find out whether all clinical cancers go through a prolonged in-situ stage and if we can find out whether those that are fatal have the same pre-clinical period as those that are cured, we shall have learnt a great deal about the cancer process which will be invaluable in developing our understanding of the mechanism by which the disease is produced, as well as having provided an indication of the prophylactic value of cytological screening.

Four points struck me as of particular interest, amongst the many that have been raised by the opening speakers.

(1) The need to measure the benefit of screening procedures by changes in the death rate. Unless the death rate is affected, the prophylactic measures have done very little. They may, indeed, have made some patients more comfortable, and they may have enabled minor operations to be substituted for major ones; but unless they can affect the death rate they have failed in their main objective. I wonder, therefore, whether any of the speakers has any knowledge of what has been happening to the death rate from cancer of the cervix in British Columbia since 1960. The last figures I have seen relate to 1960, when there was sadly little demonstrable change in the death rate, despite the intensive screening that had been going on for some five years.

(2) In the case of cancer of the lung, the biggest advance may well be made when cytologists are able to detect cells in the sputum, which correspond to those found with the in-situ stage of cancer of the cervix. If we can pick up such changes and if we can accept Auerbach's work (Auerbach *et al.* 1962), which suggests that with the cessation of cigarette smoking in-situ changes in the bronchi disappear, we can then tell affected patients that they personally have, say, a 50% chance of developing the disease within five years. If we could do this, we would have a much better chance of success in getting people to change their smoking habits than if we go to them, as we have to now, and say only that they have a 12% chance of developing the disease in, say, thirty years.

The potential value of repeated mass X-rays, which Dr Brett has studied so admirably, is, I fear, small. The main conclusion from his study appears likely to be that repeated radiography will not influence the death rate – a sadly negative conclusion but nevertheless one of great value. To be quite sure we shall, of course, have to wait until the remaining 10% of people have been traced and his final figures are available.

One of the difficulties in interpreting Dr Brett's study is that by intensive radiology he may well have discovered cases of lung cancer that would otherwise have been missed, so that some deaths which would erroneously have been attributed to some other cause have, as a result of the study, been attributed to lung cancer. In other words, the very nature of the study has biased it against himself. I suspect that in this country relatively few deaths from lung cancer are now attributed to other causes; nevertheless, the possibility of bias remains. If anyone can think how a study can be designed which will eliminate bias, it would be most interesting to hear of it.

(3) I should like to congratulate the speakers on the high response rates they have obtained when they have tried to get people to attend for cytological investigations – and particularly to attend for the second and third time. In our experience the best we have been able to get in London is a 50% response – and this only by repeated letters and home visiting.

(4) I should like to ask Dr Dunn two questions. He has that fascinating group of cases which appeared as invasive cancer after two negative screenings. Can he tell us how aggressive these cancers have been? Have they been a more fatal group than those discovered in ordinary practice? One might hope that these cancers would be early and have a 100% cure rate, but if they were not, and if the fatality rate was high, it would be of great biological interest.

Lastly, I should like to ask him whether it is sufficient to compare the sum of the areas under the incidence curves of in-situ carcinoma and beginning invasive carcinoma with the area under the incidence curve of the clinically diagnosed carcinoma, to say that the former groups would eventually constitute the latter if left alone. Does not one also have to compare time changes and show that at any given age the reduction in the prevalence rate of in-situ carcinoma plus its incidence rate is equal to the incidence of clinical invasive cancer? From such preliminary impressions as one can have from looking at the curves he has presented, I have some doubt whether it would, in fact, work out this way. If it does, I think that he has gone a long way to showing that there is a steady progression from one stage into the other. Otherwise I think it remains possible that the in-situ carcinoma is biologically a different entity; that many cases would regress if left alone; that those that turn into cancer – as some undoubtedly do – turn into the sort of cancers which are most easily treatable, and that the fatal cancers are those that arise *de novo* six months after having been negative on cytological screening. I am not saying that that is probable, but I think it remains a possibility; and until we have conclusive evidence we must still put a question mark against the benefit of the effort that is going into cancer screening.

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Dr J E Dunn (*California*) in reply, said that in connexion with the death rate in British Columbia, which also applied to Memphis and San Diego, they had not at the moment seen any definite effect on mortality as far as cervical cancer was concerned. It had been reported earlier from British Columbia that there had been some evidence of it, but they had a very erratic death rate and recently had computed in a different way a three-year running average which made it fairly level.

They would not expect a precipitous change in the death rate from cervical cancer. When a cytological programme was started nearly all future cancer deaths for the next few years were already known in the population. These were the prevalent cases of diagnosed disease; they would go on dying of the disease regardless of any project.

Secondly, it took quite a time to build up a very large portion of the population as the screened population. In Memphis it had taken five or six years to get 50% of the population included in at least one cytology examination. In British Columbia, they had really got going on a large scale only about 1960. There was still the possibility that the improvement in the death rate would appear later and, perhaps, it should not be expected at the moment.

Dr Dunn said the difficulty they had had in the United States was that cervical cancer death rates were decreasing everywhere so that they had the problem of trying to decide whether the death rate was going down faster in the screened populations than in the rest of the population. Furthermore, cytological screening was being done quite extensively. The Cancer Society had done a study in 1961 in which they had found that about one-third of all adult women in the United States had had at least one cytological examination. In Alameda County, which was the county adjoining Berkeley, a study done at about the same time had shown that 50% of the women there had been screened. There had never been any programme in Alameda County to promote the use of cytology. In San Diego, the proportion was 62% in the city and about 70% in the county. So although they were looking at population groups which were being screened more intensely than the rest of the population, the rest of the population was not being neglected.

In reply to the second question regarding invasive cancers Dr Dunn said it was disappointing to find that some cervical cancers began in a very aggressive manner and were invasive when they first turned up with positive cytology and biopsies were taken. There should be no surprise at this. They saw cancers in all stages of aggressiveness in all sites and this should be expected in the cervix as well.

This would be a very important group when the outcome was known, but Dr Dunn could not say what it was now. There was not a large number of cases. This raised the question, however, whether there would be a component of new disease for which not even cytology would change the course.

Dr J M G Wilson (*London*) referred to Dr Pedersen's mention of the vital matter of the proportions of the population that attend or stay away from cervical cancer screening examinations. He said this was a matter of considerable concern in Great Britain. Dr Doll had mentioned that in one survey only 50% of those women invited to attend for examination had turned up. Dr Wilson said he knew of another case-finding survey which had not quite come up even to that figure. Unfortunately the women who stay away may be the very people most in need of examination.

In the Alameda County screening programme, Dr Wilson said, Dr Dunn had stated that no special health education had been given beforehand to prepare the population, so that health education had not contributed to the high attendance rate. However, Dr Wilson believed that a study on attitudes to cytology had been carried out in Alameda County and he wondered whether this in itself might not have had an educational effect and thus raised attendance.

Dr Dunn replied that in regard to Alameda County the survey had been done with an idea of trying to find out how much the population had benefited from a cytological examination. It had to be remembered that, certainly in California, very limited facilities were available for the indigent population. This was true in Alameda County, although it had some cytology service available in its county health department. Most of the women who had been examined were in the upper socio-economic range.

In Memphis, Dr Dunn said, the vaginal pool specimen was used which had been collected by technicians from almost any patient found anywhere who could be persuaded to submit to examination, and their response there had been good.

He did not think that they had the answers yet about how to influence women in the lower socio-economic groups to ask for this kind of examination. They had had some interest in the Davis self-administered kit technique. It had not been used in California. There had been some attempts to evaluate it, and Dr Dunn thought that one of these had been done in Miami. His own feeling was that the wrong people had been asked to evaluate it. He thought that Memphis should have been one of the places where this was done, because they were used to looking at a vaginal pool specimen. Some of the reports which he had recently seen from England indicated that this required a retraining of technicians. Memphis would have been the logical place. Attempts to compare vaginal pool with cervical scraping had usually been done by people accustomed to using a cervical scraping, and he did not trust their evaluation. Certainly, Memphis rates looked very comparable to those of British Columbia, but British Columbia used cervical scraping and Memphis used the vaginal pool. The vaginal pool was over-read, and in every case which gave a Class 2 result a specimen was taken directly from the cervix. Dr Dunn thought, therefore, that there was a good deal in the laboratory's experience with the kind of specimen used.

Professor L G Whitby (*Edinburgh*) said that no discussion on presymptomatic diagnosis would be complete without some reference to the Varmland health-screening project (Jungner 1966) which had been carried out on a normal population, or to admission profiles of chemical tests carried out on all patients when first admitted to hospital (Bryan *et al.* 1966), or to regular checks on individuals arranged as part of a health insurance programme (Collen 1966). All these studies had demonstrated the particular value of chemical investigations in the early detection of disease.

Professor Whitby asked whether any of the speakers would comment on the generalization that serum enzyme determinations, exfoliative enzymology and isoenzyme investigations (on serum or on special materials) had proved disappointing in the early detection of neoplastic disease.

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Dr Doll said, in reply, that he thought everybody would agree that examination of enzymes in the vaginal secretion was not at present a satisfactory substitute for cytological examination.

The Chairman, in concluding the discussion, said that he had wondered at one time whether the risks of X-rays might not outweigh the advantages of early diagnosis, but he was satisfied that that was not a factor which ought to be considered. Even if investigations of that kind appeared to have little practical value at present, it ought always to be remembered that it could not be foreseen what might be the uses of many of the data which had been presented.

He was ever mindful of Lord Rutherford's observation when he was investigating the emanations from uranium. Having made this important discovery, he observed: 'Thank God, this can be no damned use to anyone.'

This was why it was so necessary to try to determine whether earlier diagnosis improved ultimately the outlook for life. If it did, then clearly any objection which was raised on the grounds of producing a cancer phobia was surely invalid, because it was better to frighten people to life than frighten them to death.